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HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			SALVOZA, M	SALVOZA, M FRANCO G	
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•			1648		
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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)			
Office Action Summan	10/822,613	SCARPACE ET AL.			
Office Action Summary	Examiner	Art Unit			
	M. Franco Salvoza	1648			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
3) Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims	·				
4)	vn from consideration.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	epted or b) objected to by the drawing(s) be held in abeyance. Serion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	-				
Paper No(s)/Mail Date <u>10/11/05</u> . 6) U Other:					

• Art Unit: 1648

DETAILED ACTION

Claims 1-3, 7, 12 and 25 have been amended. New claims 31-40 have been added.

Claims 1-12 and 21-40 are pending and under consideration.

Claim Objections

WITHDRAWN

Claims 1, 30 have been objected to for reciting instructions.

Applicant argues that the objection to the claim is utterly without foundation and are mystified by reasoning that the claim should be objected to, arguing there is no requirement under U.S. law of which the applicants are aware that all elements of a claim be "functionally related."

Applicant's arguments are considered and found persuasive. The objection is withdrawn.

Claim 11 has been objected for failing to limit the subject matter of a previous claim.

Applicant argues misunderstanding as to why the Office has taken the position that claim 11 does not further limit claim 1.

Applicant's arguments are considered but found persuasive. The objection is withdrawn.

Claim Rejections - 35 USC § 101

MAINTAINED

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 29 was rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant argues that the invention of a recombinantly-engineered genetic viral vector that comprises a promoter and a heterologous DNA sequence that encodes a mammalian polypeptide is clearly a product of human ingenuity and invention, and Applicant needs not be required to further limit the claim by amendment to indicate the hand of the inventor.

Applicant's arguments are considered but found unpersuasive. The issue is not whether or not the hand of man is involved in an invention reciting a mammalian host cell comprising the composition comprising a recombinant adeno-associated viral vector that comprises a nucleic acid segment encoding a pro-opiomelancocortin polypeptide – that much is clear. The issue is what type of subject matter the claim reads on (emphasis added). The claim reads on a human being comprising the cell, and human beings may not be claimed.

Therefore, the rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 112

MAINTAINED

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 21-30 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of rAAV-POMC compositions to the hypothalamic arcuate nucleus of rats, does not reasonably provide enablement for the other

claimed methods of delivery (for example, intramuscular). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant argues that there is no requirement under the law that the Specification enable all practical uses of the disclosed compositions; that all that is required to enable the claimed invention is an objective teaching concerning the polynucleotide compositions and specific guidance concerning how to make and use the claimed compositions in a substantial, credible way; the specification enables the in vivo use of the disclosed rAAV-POMC compositions in the obese Zucker rat animal model; this result by itself is sufficient to enable the claimed compositions and provide enablement of a clear, substantial and credible utility; since the vectors are fully enabled, anything else that comprises such viral constructs are also de facto enabled and the requirement of providing a substantial and credible utility has been met; that applicant needs not provide all possible utilities to satisfy the "use" requirement, nor need they enable all possible utilities of the claimed compositions.

Applicant also argues that the specification need not provide human test data.

Applicant's arguments are considered but found unpersuasive.

First, applicant is not required to enable all practical uses of the disclosed compositions, but rather the claimed subject matter. Claim 10 recites the composition of claim 1 formulated for administration to a human; Claim 22 recites the composition of claim 10 formulated for intramuscular, intravenous, intrathecal, or intracerebroventricular administration; Claim 23 recites the composition of claim 22, formulated for intracerebroventricular administration to the

arcuate nucleus of a mammalian hypothalamus. The specification only discloses (p. 69) an example of the injections directly into the hypothalamic arcuate nucleus of rats.

Second, enablement, utility and enablement of utility are separate issues in regards to patentability and seemingly confused by applicant. In regards to a 112 1st P rejection, concepts of utility are not relevant – the issue is whether or not applicant has provided sufficient disclosure as to enable all recitations of the claimed invention. As indicated above, Claim 10 recites the composition of claim 1 formulated for administration to a human; claim 22 recites the composition of claim 10 formulated for intramuscular, intravenous, intrathecal or intracerebroventricular administration, while the specification only teaches an example of the injections directly into the hypothalamic arcuate nucleus of rats (p. 69). For example, in regards to intracerebroventricular administration, the specification has not provided sufficient details disclosing how the blood-brain barrier has been overcome, reciting only injections directly into the hypothalamic arcuate nucleus of rats.

Furthermore, applicant's attention is directed towards page 4 of the First Office Action on the Merits indicating a *scope* of enablement (emphasis added) rejection, not an enablement rejection outright. Therefore, the application may be enabled as to some claim uses, but not to others, but nonetheless a scope of enablement rejection is proper.

In addition, applicant is correct in asserting that human test data need not be submitted. However, the enablement rejection is determined after a weighing of several possible factors (see See, In re Wands, 8 USPQ 2d 1400, at 1404 (CAFC 1988) and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986).

Art Unit: 1648

Therefore, the rejection is withdrawn as to claim 23, but maintained as of record to claims 1-12, 21, 22, 24-30.

Claim Rejections - 35 USC § 103

MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 11, 12, 21, 24 and 26-30 were rejected under 35 U.S.C. 103(a) as being obvious over Pritchard et al. in view of Paterna et al.

Applicant argues that since Pritchard does not mention any type of viral vector compositions, AAV-based viral vector compositions, the construction of rAAV viral particles, the reference fails to provide the relevant teaching, suggestion, expectation of success and motivation to combine with Paterna et al. to render obvious the claimed invention.

Further, applicant also argues that Paterna et al. is not available under 102 (b), but only under 102(a). Applicant also argues that Paterna et al. does not teach or suggest POMC-derived peptides, polypeptides or DNA sequences encoding them.

Applicant's arguments are considered but found unpersuasive.

First, Pritchard et al. does not need to mention the vector to be properly combinable with Paterna et al.. Nor does Paterna et al. need to suggest POMC-derived peptides. The 103 rejection is over *a combination of references* (emphasis added). Each reference does not need to teach

each and every single limitation of every claim in a 103 rejection, rather the rejection is based on a combination of the cited references that are linked through motivation to combine and reasonable expectation of success, wherein the *combination* (emphasis added) meets all limitations of the recited invention.

Thus, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Furthermore, a 102(a) reference is proper for use in a 103 rejection. As applicant stated himself on p. 22 of applicant's remarks, "the reference must be available for citation under at least one provision of 102." Applicant is asked to explain why such a distinction between 102(a) and 102(b) is necessary for 103 purposes.

Additionally, based on the state of the art at the time, it was known by those of ordinary skill that an increase in POMC gene expression and POMC polypeptides played a role in melanocortin regulation and weight gain (Pritchard et al., (2002) p. 418; see also Dhillon et al. cited in support of Pritchard et al., "Dose-dependent effects of Central Leptin Gene Therapy on Genes that regulate body weight and appetite in the Hypothalamus," *Molecular Therapy*, Vol. 4, No. 2 (2001), published one year previously to Pritchard et al.; Bagnasco et al. cited in support of Pritchard et al., "Evidence for the existence of distinct central appetite, energy expenditure, and ghrelin stimulation pathways, as revealed by hypothalamic site-specific leptin gene therapy," *Endocrinology* 143(11): p. 4409-4421 (2002)).

Dhillon et al. supports the teachings of Pritchard et al. to teach that a high dose of localized rAAV-leptin injections (leading to enhanced POMC mRNA expression and expression of POMC peptides) directly to the hypothalamic arcuate nucleus in rats would lead to a reduction in body weight, decrease in food take, and otherwise suppression in weight gain (Dhillon et al.: abstract, p. 140, 142, 143.) Dhillon et al. specifically recites, "Leptin enhances POMC mRNA expression in wild-type rodents, Lepob/ob mice and Lepob/ob mice treated intravenously with rAAV-leptin. Upregulation of ARC POMC mRNA after the high dose icv rAAV-leptin injection suggests that suppression of food intake may be the combined effect of decreased NPY and increased melanocortin signalings" (p. 143).

Bagnasco et al. also teaches: "We observed that rAAV-lep injection in the ARC decreased NPY and increased POMC gene expression in association with a sustained decreased food intake (p. 4419).

In regards to Paterna et al., Dhillon et al. and Bagnasco et al. are also cited in support to show that rAAV vectors were known in the art at the time and commonly used for gene therapy and targeted peptide expression, especially in the mammalian brain, as taught by Paterna et al.

Therefore, one of ordinary skill in the art at the time would not only have had a motivation to combine the POMC gene and peptide of Pritchard et al. (the gene expression of which lead to results known in the art at the time explained above as cited by Pritchard et al., Dhillon et al. cited in support of Pritchard et al., and Bagnasco et al. cited in support of Pritchard et al.) and the recombinant AAV vectors of Paterna et al. (again, known in the art at the time of invention), but one of ordinary skill in the art would have also had even further motivation to

Art Unit: 1648

combine the two in order to advance a step in the signaling pathway by starting with the POMC gene expression, and not just the leptin, the signaling precursor to POMC.

One or ordinary skill in the art at the time of invention would also have had a reasonable expectation for success based on the teachings of Pritchard et al., Dhillon et al. cited in support of Pritchard et al., Bagnasco et al. cited in support of Pritchard et al., and Paterna et al. as explained above.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

The rejection is maintained for reasons of record.

Claims 1-9, 21, 26 and 27 were rejected under Pritchard et al. and Paterna et al. and further in view of Lasic.

Applicant argues that the addition of the secondary reference of Lasic fails to obviate the claimed invention since certain claims to not even claim liposomes or microspheres. Second, Lasic contains no motivation to combine its teachings with Paterna et al. or Pritchard et al.

Applicant's arguments are considered and found persuasive as to 1-7, 21, 26 and 27 since said claims do not recite liposomes or microspheres, but unpersuasive as to claims 8 and 9.

The 103 rejection is over *a combination of references* (emphasis added). Each reference does not need to teach each and every single limitation of every claim in a 103 rejection, rather the rejection is based on a combination of the cited references that are linked via a motivation to combine and reasonable expectation of success, wherein the *combination* (emphasis added) meet all limitations of the recited invention.

Art Unit: 1648

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

See also the teachings of Pritchard et al., Dhillon et al. cited in support of Pritchard et al., Bagnasco et al. cited in support of Pritchard et al., and Paterna et al. above.

The rejection is maintained for claims 8 and 9 for reasons of record.

Claims 1-7, 11, 12, 21-24, 26-28 and 30 were rejected under Pritchard et al. and Paterna et al. further in view of Keir et al.

Applicant argues that the addition of the secondary reference of Keir et al. fails to obviate the claimed invention since certain cited claims do not even claim intracerebroventricular administration or delivery to the hypothalamus. Second, Keir et al. contains no motivation to combine its teachings with Paterna et al. or Pritchard et al.

Applicant's arguments are considered and found persuasive as to 1-7, 11, 12, 21, 24, 26-28, 30 since said claims do not recite liposomes or microspheres, but unpersuasive as to claims 22 and 23.

The 103 rejection is over *a combination of references* (emphasis added). Each reference does not need to teach each and every single limitation of every claim in a 103 rejection, rather the rejection is based on a combination of the cited references that are linked via a motivation and reasonable expectation of success, wherein the *combination* (emphasis added) meet all limitations of the recited invention.

Art Unit: 1648

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

See also the teachings of Pritchard et al., Dhillon et al. cited in support of Pritchard et al., Bagnasco et al. cited in support of Pritchard et al., and Paterna et al. above.

The rejection is maintained as to claims 22 and 23 for reasons of record.

Claims 1-8, 11, 12, 21-24, 26-28 and 30 were rejected under Pritchard et al. and Paterna et al. further in view of Russell et al.

Applicant argues that the reference does not suggest or provide any motivation to combine its teachings with respect to the primary references Paterna et al. and Pritchard et al..

Applicant's arguments are considered but found unpersuasive. The 103 rejection is over *a* combination of references (emphasis added). Each reference does not need to teach each and every single limitation of every claim in a 103 rejection, rather the rejection is based on a combination of the cited references that are linked via a motivation to combine and reasonable expectation of success, wherein the *combination* (emphasis added) meet all limitations of the recited invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Application/Control Number: 10/822,613 Page 12

Art Unit: 1648

See also the teachings of Pritchard et al., Dhillon et al. cited in support of Pritchard et al.,

Bagnasco et al. cited in support of Pritchard et al., and Paterna et al. above.

The rejection is maintained for reasons of record.

Applicant's arguments 2.8.7 labeled "The Claims Distinguish Over the Prior Art"

Applicant argues that the 103 rejection cannot stand; the suggestion and reasonable expectation must be founded in the prior art; the combination of references fails to satisfy the tripartite test of In re O'Farrell.

Applicant's arguments are considered but found unpersuasive. See the teachings of Pritchard et al., Dhillon et al. cited in support of Pritchard et al., Bagnasco et al. cited in support of Pritchard et al., and Paterna et al. above.

Claim Objections

NEW, necessitated by amendment

Claim 37 is objected to because of the following informalities: Claim 37 contains a typo reciting "serotype 4, serotype 5, or serotyp6 vector." Appropriate correction is required.

Claims 31, 32 are objected to because of the following informalities: It is noted that the "instructions" are a physical component of the claimed kit, but are not patentable because they are not functionally related to the instant polypeptide, see *In re Gulack*, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983). Appropriate correction is required.

Claim Rejections - 35 USC § 112

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NEW, necessitated by amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 35 and 36 also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of rAAV-POMC compositions to the hypothalamic arcuate nucleus of rats, does not reasonably provide enablement for other methods of delivery (for example, intramuscular). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

See the enablement rejection of claims 1-12, 21, 22, 24-30 above. The rejection applies to new claims for the reasons of record.

Claim Rejections - 35 USC § 103

NEW, necessitated by amendment

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-40 are rejected under 35 U.S.C. 103(a) as being obvious over Pritchard et al. in view of Paterna et al.

Art Unit: 1648

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Claim 31 recites the kit comprising in suitable container means the composition of claim 1; and instructions for using said kit; claim 32 recites a kit comprising in suitable container means: (a) composition that comprises an adeno-associated viral vector comprising a nucleic acid segment that encodes a pro-opiomelanocortin polypeptide operably linked to a promoter capable of expressing said segment in a mammalian host cell, and (b) instructions for using said kit in the diagnosis, prevention, or treatment of a pro-opiomelanocortin polypeptide deficiency in said mammalian host cell.

Claims 33, 34, 37, 40 recite the composition of claim 1 wherein said mammal has been diagnosed with obesity, adiposity, or suffers from excessive body weight gain; wherein said mammal has a pro-opiomelanocortin polypeptide deficiency condition that results in polyphagia, hyperinsulemia, adiposity, an eating disorder, or body weight gain in said mammal; wherein said adeno-associated viral vector is a serotype 1, serotype 2, serotype 3, serotype 4, serotype 5, or serotype 6 vector; wherein said promoter comprises a chicken beta-actin promoter.

Claim 35 recites the composition of claim 6 formulated for intramuscular, intravenous, intrathecal, or intracerebroventricular administration to said mammal; claim 36 recites the composition of claim 35 formulated for administration to a human.

Claim 38 recites the composition of claim 2, wherein said enhancer sequence comprises a cytomegalovirus immediate early enhancer sequence; claim 39 recites the composition of claim 3, wherein said post-transcriptional regulatory element comprises a woodchuck hepatitis virus post-transcriptional regulatory element.

In the prior Action, Pritchard et al. was cited as teaching the use of MHC4, a mammalian POMC peptide that plays a role in the melanocortin pathway in the hypothalamus. Pritchard et

Art Unit: 1648

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al. also teaches the evidence of regulation of POMC peptides towards regulation of obesity, a similar condition to polyphagia (excessive eating), hyperinsulemia (excessive insulin), adiposity (fat-containing), an eating disorder or body weight gain. Pritchard et al. also teaches the analysis of fed and fasted Wistar rats and lean and obese Zucker rats (p. 417).

See also the teachings of Dhillon et al. and Bagnasco et al. both cited in support of Pritchard et al. above.

Pritchard et al. does not teach the use of the recombinant adeno-associated vectors.

In the prior Action, Paterna et al. was cited as teaching the use of recombinant adenoassociated vectors and virions as a means for gene therapy, expression and delivery, as well as
the transcriptional regulatory elements, enhances, promoters in compositions and kits for
transfection into host cells. Paterna et al. also teaches the use of the vector in a composition,
which anticipates the recitation to the kit as in claims 31 and 32 well. Paterna et al. also teaches a
cytomegalovirus enhancer sequence (p. 213) as well as wood chuck hepatitis B virus posttranscriptional regulatory element (p. 214). Paterna et al. also teaches the use of various
serotypes such as 2, 4 and 5 and further recites transduction with all rAAV serotypes (p. 211).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the POMC peptide of Pritchard et al. and the adeno-associated viral vector of Paterna et al. because Paterna et al. teaches a method to package and deliver specific genes.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the pro-opiomelanocortin peptide of Pritchard et al. with the recombinant adeno-associated vector of Paterna et al. because Pritchard et. al. and Paterna et al. both teach using potential methods of gene therapy.

Application/Control Number: 10/822,613

Art Unit: 1648

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Application/Control Number: 10/822,613

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvez Patent Examiner May 5, 2006

> BRUCE R. CAMPELL, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

Brune Campell